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[Signature]  
Gerard J. McGowan, Jr.  
Reg. No. 29,412  
Attorney for Applicant(s)

7/16/04  
Date of Signature

**PATENT**

CASE #F7590(V)  
UNUS #01-0367-UNI

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Van Oorschot et al.  
Serial No.: 10/072,570  
Filed: February 8, 2002  
For: PROCESS FOR THE PREPARATION OF ONE OR MORE  
STATINS BY FERMENTATION

Group: 1617  
Examiner: Edward A. Webman  
EDGEWATER, NEW JERSEY 07020

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Documents relating to the above-identified application are submitted herewith. These documents are intended for the Examiner's information and for citation with the instant case. This submission does not constitute either a representation that a thorough search has been made or an admission that the documents cited herein are properly citable against the above-captioned patent application. Any comments accompanying the document are not intended to take the place of the Examiner's

independent consideration of each document. An attached PTO Form 1449 lists all the documents.

European Search Report dated October 25, 2001 on EP 01 20 0489

Manzoni et al., "Production of Statins by Filamentous Fungi", Biotechnology Letters, Kew, Surrey, GB, Vol. 21, 1999, pp. 253-257

EP 0 517 413 A

Yongsmith Basaba et al., "Color Mutants of Monascus sp. KB9 and their Comparative Glucoanylases on Rice Solid Culture", J. Molec. Catal B; Journal of Molecular Catalysis B: Enzymatic Sep 2000 Elsevier Science B.V., Amsterdam, Netherlands, Vol. 10, No. 1, September 2000, pp. 263-272

Manzoni et al., "Production and Purification of Statins from Aspergillus Terreus Strains", Biotechnology Techniques, Chapman & Hall, XX, Vol. 12, No. 7, July 1998, pp. 529-532

Elkin et al., "Reduction of the Cholesterol Content of Eggs by the Oral Administration of Lovastatin to Laying Hens", Journal of Agricultural and Food Chemistry, American Chemical Society, Vol. 38, No. 8, pp. ISSN: 0021-8561

WO 98/19555

WO 00/30665

U.S. Patent No. 6,046,022 (Zhang et al.)

Nutrition Research 18, Li et al., pp. 71-81 (1998) - mentioned on page 1 of the specification

Am. J. Clin. Nutr., 69, Heber et al., pp. 231-236 (1999) - mentioned on page 1 of the specification

Endo, J. Antibiotics 32, pp. 852-854, (1979) - mentioned on page 1 of the specification (to be sent under separate cover)

Food and Drug Administration, Administrative Proceeding, Docket No. 97P-0441;  
Final Decision

Code of Federal Regulations: 21 CFR 101.12 - Food Labeling; Reference  
amounts customarily consumed per eating occasion, 18 pages  
Gemuse Vegetables Legumes, Legumes and Oil Seeds, pg. 839, XP-002208111  
EP 1 176 208 A1  
WO 01/03647  
Endo, J. Antibiotics 32, pps. 852-854, (1979)

Since a first Office Action on the merits has already issued, please consider the information and charge the \$180.00 fee under 37 CFR §1.117(p) to Deposit Account No. 12-1155. Please charge any additional fees or credit overpayment to Deposit Account No. 12-1155. Triplicate copies of this letter are enclosed.

Respectfully submitted,

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FORM PTO-1449

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

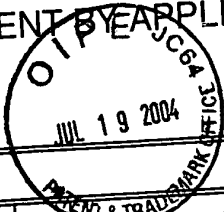
ATTORNEY DOCKET NO.. F7590(V)

SERIAL NO.: 10/072,570

APPLICANT: Van Oorschot et al.

FILING DATE: February 8, 2002

GROUP: 1617



## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIALS | DOCUMENT NO. | DATE      | NAME OF INVENTOR | CLASS        | SUBCLASS | FILING DATE<br>IF<br>APPROPRIATE |
|----------------------|--------------|-----------|------------------|--------------|----------|----------------------------------|
|                      | 1            | 6,046,022 | 4/00             | Zhang et al. |          |                                  |
|                      |              |           |                  |              |          |                                  |
|                      |              |           |                  |              |          |                                  |

## FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIALS | DOCUMENT NO. | DATE      | COUNTRY | CLASS  | SUBCLASS | TRANSLATION<br>YES OR NO |
|----------------------|--------------|-----------|---------|--------|----------|--------------------------|
|                      | 2            | 0 517 413 | 12/92   | Europe |          |                          |
|                      | 3            | 98/19555  | 5/98    | WO     |          |                          |
|                      | 4            | 00/30665  | 6/00    | WO     |          |                          |
|                      | 5            | 1 176 208 | 1/2     | Europe |          |                          |
|                      | 6            | 01/03647  | 1/01    | WO     |          |                          |
|                      |              |           |         |        |          |                          |

## OTHER DOCUMENTS

|    |  |
|----|--|
| 7  | European Search Report dated October 25, 2001 on EP 01 20 0489   |
| 8  | Manzoni et al., "Production of Statins by Filamentous Fungi", Biotechnology Letters, Kew, Surrey, GB, Vol. 21, 1999, pp. 253-257   |
| 9  | Yongsmith Basaba et al., "Color Mutants of Monascus sp. KB9 and their Comparative Glucoamylases on Rice Solid Culture", J. Molec. Catal B; Journal of Molecular Catalysis B: Enzymatic Sep 2000 Elsevier Science B.V., Amsterdam, Netherlands, Vol. 10, No. 1, September 2000, pp. 263-272 |
| 10 | Manzoni et al., "Production and Purification of Statins from Aspergillus Terreus Strains", Biotechnology Techniques, Chapman & Hall, XX, Vol. 12, No. 7, July 1998, pp. 529-532  |
| 11 | Elkin et al., "Reduction of the Cholesterol Content of Eggs by the Oral Administration of Lovastatin to Laying Hens", Journal of Agricultural and Food Chemistry, American Chemical Society, Vol. 38, No. 8, pp. ISSN: 0021-8561   |
| 12 | Nutrition Research 18, Li et al., pp. 71-81 (1998) - mentioned on page 1 of the specification  |
| 13 | Am. J. Clin. Nutr., 69, Heber et al., pp. 231-236 (1999) - mentioned on page 1 of the specification  |
| 14 | Endo, J. Antibiotics 32, pp. 852-854, (1979) - mentioned on page 1 of the specification  |
| 15 | Food and Drug Administration, Administrative Proceeding, Docket No. 97P-0441; Final Decision   |
| 16 | Code of Federal Regulations: 21 CFR 101.12 - Food Labeling; Reference amounts customarily consumed per eating occasion, 18 pages   |
| 17 | Gemuse Vegetables Legumes, Legumes and Oil Seeds, pg. 839, XP-002208111  |
| 18 | Endo J. Antibiotics 32, pp. 852-854 (1979) (to be sent under separate cover)   |

EXAMINER

DATE CONSIDERED

EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THOROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.